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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/807,489	07/31/2001	Isabel Antonia Maria Van Waterschoot	01-468	9467

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EXAMINER	
GHALI, ISIS A D	

ART UNIT	PAPER NUMBER
1615	

DATE MAILED: 08/29/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/807,489	VAN WATERSCHOOT ET AL.	
	Examiner	Art Unit	
	Isis Ghali	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *19 June 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-4,6,7,15,18-21 and 25-30* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-4,6,7,15,18-21 and 25-30* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *06/19/06*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

The receipt is acknowledged of applicants' amendment and request for RCE, both filed 06/19/2006.

Claims 5, 8-14, 16, 17 and 22-24 have been canceled.

Claims 29 and 30 have been added.

Claims 1-4, 6, 7, 15, 18-21, and 25-30 are included in the prosecution.

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 06/19/2006 has been entered.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. Claim 18, and 26-30 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for promoting lactation in pregnant or lactating non-human female mammal by administering ARA in an edible formulation, does not reasonably provide enablement for promoting lactation in all non-human female mammal by administering the same, as claimed in claim 18. Furthermore, the specification has enabled administering ARA for promoting lactation in pregnant or lactating non-human female mammal, but has not enabled prevention of any diseases or conditions associated with PUFA deficiency, as claimed in claims 26-30. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with these claims.

The factors to be considered in determining whether a disclosure meets the enablement requirement of 35 U.S.C. 112, first paragraph, have been described in *In re Wands*, 8 USPQ2d 1400 (Fed. Cir. 1988). Among these factors are: the nature of the invention; the breadth of the claims; the state of the prior art; the relative skill of those in the art; the amount of direction or guidance presented; the predictability or unpredictability of the art; the presence or absence of working examples; and the quantity of experimentation necessary. When the above factors are weighed, it is the examiner's position that one skilled in the art could not practice the invention without undue experimentation.

The nature of the invention: The nature of the invention is an edible formulation such as a dietary supplement comprising microbial ARA by itself or in combination with and DHA and method of its use for pregnant or lactating non-human female mammal to promote lactation.

The breadth of the claims: The claims are broad. Claim 18 encompasses promoting lactation in non-pregnant and non-lactating non-human female mammals. Claims 26-30 encompass promotion and/or prevention of conditions and disorders that may have other potential causes and not associated with pregnancy and lactation. This may or may not be addressed by the administration of the instant edible formulation comprising ARA. The specification is directed to dietary supplement for pregnant or lactating mammals, however, other disorders are encompassed by reciting: "diseases and conditions" including nursed infant malnutrition. The specification has enabled lactation promotion, but not prevention or cure of associated conditions that may encompass infant malnutrition. On page 6, lines 10-12, applicants disclosed that ARA is used for non-human mammal which is pregnant or lactating. Therefore, applicants disclosed only one use of ARA in the non-human mammals as a nutritional supplement for pregnant and lactating females.

The state of the prior art: The state of the art does not recognize the administration of composition comprising ARA to prevent, ameliorate or treat any condition or disease associated PUFAs deficiency in pregnant or lactating non-human female mammals. The state of the art recognizes administration of dietary supplement comprising ARA and DHA to the pregnant and lactating human and animals, but not

preventing associated conditions or diseases, or their cure, US 6,200,624, WO 98/16119 and WO 96/21037.

The relative skill of those in the art: The relative skill of those in the art is high.

The amount of direction or guidance presented: The guidance given by the specification on how to prevent, ameliorate or treat any condition or disease associated PUFAs deficiency in non-human mammals female is absent. The guidance given by the specification on how to promote lactation in non-pregnant or non-lactating mammals is absent. No evidence is provided regarding preventing all conditions associated with PUFA deficiency. No evidence is provided regarding promotion of lactation in all non-human mammals, even non-pregnant or non-lactating. It is not obvious from the disclosure of promoting lactation in pregnant and lactating non-human female mammals if promotion of lactation in all non-human mammals will be promoted by oral administration of PUFAs. It is not obvious from the disclosure of promoting lactation in pregnant and lactating non-human female if other conditions or diseases associated with PUFAs deficiency will be treated by oral administration of PUFAS. A disclosure should contain representative examples which provide reasonable assurance to one skilled in the art that the conditions fall within the scope of a claim will be treated by the claimed composition. See *In re Riat et al.* (CCPA 1964) 327 F2d 685, 140 USPQ 471; *In re Barr et al.* (CCPA 1971) 444 F 2d 349, 151 USPQ 724.

The predictability or unpredictability of the art: The lack of significant guidance from the specification or prior art with regard to prevention of all conditions or

diseases associated with PUFAs deficiency makes practicing the claimed invention unpredictable in terms prevention of condition and in terms of what conditions.

The presence or absence of working examples: The specification discloses only edible oral formulation comprising ARA and/or DHA used for pregnant and lactating mammals, examples 1-6. No working examples to show formulations administered to non-pregnant or non-lactating mammals to promote lactation. No working examples to show prevention of conditions associated with PUFA deficiency, or their cure. Therefore, the specification has only enabled promoting lactation in pregnant and lactating mammals by orally administering composition comprising ARA and DHA in pregnant and lactating mammals; and enabled oral dietary supplement to promote lactation, but not prevention of all conditions associated with PUFAs deficiency.

The quantity of experimentation necessary: Therefor, the practitioner would turn to trial and error experimentation to practice the instant method for preventing conditions associated with PUFA deficiency without guidance from the specification or the prior art. Therefore, undue experimentation becomes the burden of the practitioner.

Response to Arguments

4. Applicant's arguments filed 06/19/2006 have been fully considered but they are not persuasive. Applicants traverse the rejection under 112 first paragraph by arguing that example 11 shows that the administration of ARA can increase essential fatty acids in an animal with induced fatty acid deficiencies, and the used mouse model shows the mice fed with ARA lead to alleviation of PUFA deficiencies in the red blood cells of the

female mice. The teaching of the present invention enable one skilled in the art to prevent or prophylaxis of diseases or conditions associated with low level of PUFAs in the blood by administering ARA to non-human mammal suffering exhibiting low level of fatty acids in the blood.

In response to these argument, the examiner position is that the claims are broad and encompass prevention of all types conditions and diseases associated with PUFA deficiency. The specification has not enabled prevention of all disease conditions associated with an abnormal or low level of PUFA in the blood. Example 11 shows amelioration of fatty acid deficiency in pregnant mouse, and not its prevention. Tables 6-8 of the specification show increase of the fatty acids in the blood but not prevention of conditions or diseases.

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claims 26-30 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claims 26-30 are confusing as they are directed to providing dietary or supplemental nutrition to the pregnant or lactating non-human female or method for promoting lactation in pregnant or lactating non-human female and meanwhile the claims recite conditions and diseases associated with low level of PUFA or ARA which not related to pregnancy or lactation.

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

8. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

9. Claims 1-4, 6, 7, 15, 18-21, and 25-30 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 6,200,624 ('624) in view of WO 98/16119 ('119) or in view of WO 96/21037 ('037).

US '624 teaches a nutritional supplement comprising ARA and DHA that can be administered to pregnant or lactating human and animal females (title, abstract; col.17, lines 31-38). The supplement comprises 0.1- 5% DHA and 1-15% ARA (col.30, lines 15-22).

US '624 does not teach the amount of each of ARA and DHA and their ratios, or the profile of administration of ARA. The reference does not teach clearly the promotion of lactation, but this limitation is implied by the teaching of administering the dietary supplement for lactating human or animal. US '624 does not teach the ARA to be microbial.

WO '119 teaches an edible formulation comprising ARA derived from microorganisms and used as foods for pregnant and lactating mothers (abstract).

WO '037 teaches ARA in very high amounts that is preferably derived from microbe and provided for pregnant and nursing women (abstract; page 4, lines 7-10). The microbial produced ARA is economical and commercially feasible method of production (page 3, lines 20-25).

It is within the skill in the art to determine the profile of administration of a pharmaceutical formulation and the amount and ratios of different ingredients in order to achieve the desired effect, absence of superior and unexpected results. Thus, the claimed amounts and ratios, and profile of use are not considered critical since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. *In re Aller,* 105 USPQ 233. It is also within the skill in the art to use formulation comprising ARA and DHA to treat conditions or disorders known to be caused by the deficiency of these fatty acids.

Therefore, it would have been obvious to one having ordinary skill in the art at the time of the invention to provide edible formulation comprising ARA and DHA for

administration for lactating and pregnant female animals as disclosed by US '624, and select the ARA from microbial origin as disclosed by WO '119 or WO '037, motivated by the teaching of WO '119 that ARA originated from micro-organisms are suitable for ingestion particularly by pregnant and lactating females, or motivated by the teaching of WO '037 that microbial produced ARA is economical and commercially feasible method of production and can be administered to pregnant and nursing females, as desired by applicants, with reasonable expectation of having edible formulation comprising microbial ARA for administration to pregnant and lactating female animals that provides the needs of the user and meanwhile produces by economic and commercially feasible method.

10. Claims 1, 2, 6, 7, 15, 18 and 26-28 are rejected under 35 U.S.C. 103(a) as being unpatentable over WO 98/16119 ('119).

WO '119 teaches an edible formulation comprising ARA derived from microorganisms and used as foods for pregnant and lactating mothers (abstract).

WO '119 does not teach the amounts and the profile of administration of ARA, or the administration to non-human mammal.

The administration to non-human mammal is implied by the teaching of the reference, and does not impart patentability to the claims, absent evidence to the contrary. It is known to use the drugs and composition of treating human and non-human mammals exchangeably.

The amounts and profiles are not considered critical since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. *In re Aller,* 105 USPQ 233.

11. Claims 1, 2, 6, 7, 15, 18 and 26-28 are rejected under 35 U.S.C. 103(a) as being unpatentable over WO 96/21037 ('037).

WO '037 teaches ARA in very high amounts that is preferably derived from microbe and provided for pregnant and nursing women (abstract; page 4, lines 7-10). The microbial produced ARA is economical and commercially feasible method of production (page 3, lines 20-25).

WO '037 does not teach the amounts and the profile of administration of ARA, or the administration to non-human mammal.

The administration to non-human mammal is implied by the teaching of the reference, and does not impart patentability to the claims, absent evidence to the contrary. It is known to use the drugs and composition of treating human and non-human mammals exchangeably.

The amounts and profiles are not considered critical since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. *In re Aller,* 105 USPQ 233.

12. Claims 3, 4,19-21 and 25 are rejected under 35 U.S.C. 103(a) as being unpatentable over any of WO '119 or WO '037 each in view of Makrides et al.

The teachings of WO '119 and WO '037 are discussed above.

WO '119 and WO '037 do not teach combining DHA with ARA, or the amount of DHA and the ratios of ARA: DHA. WO '119 and WO '037 do not teach non-human administering ARA to non-human mammals

The amount and ratios do not impart patentability to the claims, absence of superior and unexpected results. It is known to use the drugs and composition of treating human and non-human mammals exchangeably.

Makrides et al. teach method to increase the DHA in breast milk by dietary supplementation of DHA in amount 0.2-1.3 g/day.

Thus, it would have been obvious to one having ordinary skill in the art at the time of the invention to add DHA to the dietary composition comprising ARA for the pregnant or lactating female disclosed by WO '119 or WO 037, motivated by the teaching of Makrides et al. that DHA in the dietary supplement increases the DHA in the breast milk, with reasonable expectation of having a dietary supplement comprising ARA and DHA to be administered to the pregnant and lactating female to successfully and synergistically promote lactation.

Response to Arguments

13. Applicant's arguments filed 06/19/2006 have been fully considered but they are not persuasive. Applicants traverse the obviousness rejections of the claims over US

'624 by arguing that US '624 provides scant details on how or why DHA and ARA would be administered to the pregnant and/or lactating females. ARA disclosed by US '624 is not microbial. WO '119 does not each that the conditions are related to low level of ARA. WO '119 does not teach promotion of reproductive success or fertility that usually happens before pregnancy as it is administered to nursing mothers. WO '119 more likely to be administered to humans than to non-humans, with no reference to mammals other than human. Makrides combined with WO '119 do not teach the present invention.

In response to these arguments, the examiner position is that US '624 clearly disclosed "More specifically, the nutritional supplement in accordance of the present invention could be used by pregnant and/or lactating females." Regarding how it is administered, it is clearly given orally, abstract; col.7, lines 4-15; col.17, lines 32-35. Regarding why it is administered, the function is implied by administering the same formulation to the same population, i.e. pregnant and lactating females. Claiming of a new use, new function or unknown property, which is inherently present in the prior art, does not necessary make the claim patentable. Regarding the argument that US 'does not teach microbial ARA, applicant have failed to show superior and unexpected results achieved by using microbial ARA over egg derived ARA disclosed by the prior art. In any event, this argument is moot in view of the combination of US '624 in view of WO '119 that teaches ARA from microbial origin.

Regarding WO '119, the reference teaches administering microbial ARA to pregnant and nursing female. The function of the formulation is implied by administering the same formulation to the same population, i.e. pregnant and nursing females.

Regarding promotion of reproductive success, the claim language requires only one function, i.e. promotion of lactation and/or promotion or reproductivity. Regarding the argument that WO '119 teaches administration to human population the examiner is pointing out the page 7, line 3, where applicants admit the suitability of their formulation for both human and non-human mammals. In any event, it is known in the art to use animal models for biological studies and extrapolate the results to the human being. The active agents are used interchangeably between human and animals since they have similar systems. Burden is shifted to applicants to show that dietary supplement disclosed by the prior art to be administered to nursing women will not be effective in non-human from the same mammalian species.

Regarding Makrides reference, the reference is relied upon for the teaching that DHA in the diet has strong specific effect on breast milk DHA (conclusions). Therefore, the reference would have motivated one having ordinary skill in the art to include DHA in dietary supplement for nursing women. A conclusion of obviousness under 35 U.S.C. 103 (a) does not require absolute predictability, only a reasonable expectation of success; and references are evaluated by what they suggest to one versed in the art, rather than by their specific disclosure. *In re Bozek*, 163 USPQ 545 (CCPA 1969). In the light of the foregoing discussion, the Examiner's ultimate legal conclusion is that the subject matter defined by the claims would have been obvious over WO '119 in view of Makrides within the meaning of 35 U.S.C. 103 (a).

Minor Informalities

14. Claim 28 is objected to because of the following informalities: the term "or" in the 3rd line of the claim seems like it should be "of". Appropriate correction is required.

15. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Isis Ghali whose telephone number is (571) 272-0595. The examiner can normally be reached on Monday-Thursday, 7:00 to 5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward can be reached on (571) 272-8373. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Isis Ghali
Examiner
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